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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

A.F. Rothschild Fund,

Plaintiff,

v.

Department of Health and Human Services, and Centers for Disease Control and Prevention,

Defendants.

CV 11 2760

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, as amended, challenging the failure of the Department of Health and Human Services ("HHS") and the Centers for Disease Control and Prevention ("CDC") to adequately search for and release records responsive to the A.F. Rothschild Fund's ("Fund") September, 2009, FOIA request concerning the federal government's large-scale use of horses for biological production of botulism antitoxin.

Although antitoxin was discontinued for human clinical use with the introduction of antibiotics and vaccines in the 1940s, the federal government reintroduced antitoxin production in the U.S. in 2003 to procure 200,000 doses of a treatment for botulism – condemning hundreds of horses to suffer the debilitating and almost invariably fatal consequences of a federal program has no benefit to public health, is concealed from public knowledge, and for which humane alternatives are available in the unlikely event botulism were to become a public health concern. For more than a year-and-a-half, the Fund has tried to obtain the responsive records that will shed light on the government's use of horses for this program, including by initially narrowing their FOIA request. To date, Defendants have refused to produce the records to which the Fund is statutorily entitled, in violation of the FOIA.

JURISDICTION

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B). Venue in this district is proper under 28 U.S.C. § 1391(e) because Plaintiff A.F. Rothschild Fund is a registered California Nonprofit Public Benefit Corporation and maintains its headquarters and resides in this district.

INTRADISTRICT ASSIGNMENT

3. This case is properly assigned to the United States District Court, Northern District of California, San Francisco Division, as the Plaintiff is a registered California Nonprofit Public Benefit Corporation and resides and maintains its headquarters in San Mateo County, California.

PARTIES

4. The A.F. Rothschild Fund ("Fund"), formed in 1952, is an independent research and educational organization dedicated to the study of contemporary knowledge and practices relating to horses. The Fund engages in empirical research with an emphasis on the design and development of methods for objective measurement and evaluation of equine use, maintenance, and well-being. The Fund's board and members have academic and professional backgrounds in both equine and human sciences, including veterinary medicine, medical and cultural anthropology, epidemiology, genetics, ethology, and biomechanics; extensive experience with horses and equine husbandry; and a fluent understanding of their U.S. military and civilian history. The Fund recently completed development of the world's first mobile technology for three-dimensional visualization of the full body motions of free-moving horses, enabling accurate non-invasive measurement and objective evaluation of practices of equine training and equestrian use, as well as facilitating clinical diagnoses and rehabilitation of equine skeletal-muscular injuries and lameness.

5. In November 2008, the Fund initiated a study of the use of horses as a model in human medicine, focusing on the National Human Genome Research Institute's recent mapping of the equine genome. During review of federally-funded equine medical research, the Fund became aware of an undisclosed government program involving the large-scale use of horses for biological production of antitoxin, a 120-year-old pharmaceutical product derived from equine blood serum that became medically obsolete and ethically unacceptable in the U.S. three-quarters of a century ago. The Fund's FOIA request at issue here seeks records concerning the government's use of horses for this purpose.

6. The Department of Health and Human Services ("HHS") is a federal agency in control of records responsive to the Fund's FOIA request.

7. The Center for Disease Control and Prevention ("CDC") is an agency within HHS in control of records responsive to the Fund's FOIA request.

STATUTORY FRAMEWORK AND FACTS GIVING RISE TO CAUSE OF ACTION

THE FREEDOM OF INFORMATION ACT

8. "The basic purpose of FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed." John Doe Agency v. John Doe Corp., 493 U.S. 146, 152 (1989) (other citations omitted). FOIA was enacted to "permit access to official information long shielded unnecessarily from public view" by creating a "right to secure such information from possibly unwilling official hands." Environmental Protection Agency v. Mink, 410 U.S. 73, 80 (1973). "[D]isclosure, not secrecy, is the dominant objective of the Act." Id.

9. Upon request, FOIA requires agencies of the federal government to conduct a reasonable search for, and release, records to the public, unless one of nine specific statutory exemptions applies. 5 U.S.C. § 552(b). The exemptions must be narrowly construed. If an exemption applies, the agency is required to disclose "any reasonably segregable portion of the record" containing the exempt material. Id.

10. Under FOIA Exemption 3, an agency may withhold records or portions of records where disclosure is specifically exempted by another statute. Id. § 552(b)(3). In this case the agency has invoked two statutes: the Public Health Security and Bioterrorism Preparedness and

Response Act of 2002 ("Security Act"), Pub. Law 107-188, and the Public Integrity Act ("PIA"), 41 U.S.C. § 423. The Security Act contains an extremely narrow list of exempt materials permitting the withholding of information that would identify individuals possessing listed agents or toxins, or their location or related information, or any safeguards or security measures being used to prevent unauthorized access to such information. Pub. Law 107-188, § 351A(h)(1). The statute also explicitly provides that, except for this narrow list of exceptions, nothing in the Security Act may "be construed as altering the authority of any Federal agency to withhold under" the FOIA. Id. § 351A(h)(4).

11. The PIA permits an agency to withhold "contractor bid or proposal information or source selection information before the award of a Federal agency procurement contract to which the information relates." 41 U.S.C. § 423(a)(1). A "procurement contract" is limited to contracts obtained through "competitive procedures." Id. § 423(f)(4).

12. Pursuant to FOIA Exemption 4, records or portions of records may also be exempt from disclosure if the agency demonstrates that they contain "trade secrets and commercial or financial information obtained from a person and [is] privileged or confidential." 5 U.S.C. § 552(b)(4). To meet this burden, the agency must demonstrate that release of the information would either impair the government's ability to obtain necessary information in the future or cause substantial harm to the competitive position of the person from whom the information was obtained.

13. Under FOIA Exemption 5, records or portions of records may also be withheld if the agency can demonstrate they were generated prior to an agency's decision and reflect a deliberative part of the agency's decision-making process. Id. § 552(b)(5). Segregable factual portions of otherwise exempt records must be released.

14. Finally, under FOIA Exemption 6, records or portions of records may be withheld if they contain "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." Id. § 552(b)(6). The applicability of this exemption turns on a balancing of the individual's right of privacy against the basic purpose of FOIA, which is to open agency action to the light of public scrutiny.

15. Upon receiving a FOIA request, an agency has twenty working days to respond. Id. § 552(a)(6)(A). Although the agency may grant itself an extension of ten additional days in "unusual circumstances," FOIA does not permit an agency to delay a response indefinitely. Id. § 552(a)(6)(B). If a requestor appeals an agency's invocation of a FOIA exemption, the agency must respond within 20 working days. Id. § 552(a)(6)(A)(ii).

FACTUAL BACKGROUND

1. Horses and the Manufacture of Botulism Antitoxin

16. In the late nineteenth Century, scientists discovered that the blood serum of animals injected with diphtheria or tetanus toxins acted as an "antitoxin" when injected into other animals, conferring temporary protection, or "passive immunity," to the effects of the disease. The antitoxin component in the animals' blood serum, known today as "antibodies," was thought to be valuable for treating various diseases in humans, and the experiments on laboratory animals led to the large-scale commercial manufacturing of antitoxin, using horses for mass production of antibodies due to their large blood volume. In practice, antitoxin is obtained by injecting horses with sub-lethal doses of a toxin or other pathogen, to artificially induce the animal's immune system into generating large numbers of specific antibodies that counteract the effects of the injected toxin and prevent onset of the disease. The injections are repeated in a series of increased doses over a period

of months to maximize the concentration of antibodies present in the horse's blood. The animal's blood is then removed and the antibodies are extracted and purified, allowing them to be injected into human patients, in an effort to transfer the horse's immunity to the given toxin.

17. Though antitoxin was generally believed to provide a temporary therapeutic benefit for certain bacterial infections, its efficacy was speculative, it did not cure or reverse the disease, and the injection of equine blood serum into humans caused severe adverse effects. Antitoxin was rapidly abandoned beginning in the 1930s when scientists discovered far more effective, safer, and more humane methods to protect human health with vaccines. By inoculating individuals directly with a neutralized or killed form of a toxin or bacteria, the person's own immune system generates the specific human antibodies that prevent infection, conferring long-term protection to the disease prior to exposure. The elimination of major infectious diseases in the U.S. was accomplished through immunization with vaccines and not by treatment with equine antitoxins.

18. On information and belief, in response to the 9/11 and anthrax attacks, federal government officials became concerned about the potential for botulism being used in a terrorist strike, even though botulism has never successfully been turned into a weapon that could actually be used. Although a botulism toxoid vaccine has been used for more than thirty years to immunize at-risk laboratory workers and military personnel, and a human-derived antitoxin has also been developed, the government decided to stockpile large quantities of equine-derived botulism antitoxin. For example, in 2003 the federal government created the Equine Source Plasma Project ("ESPP"), and the CDC awarded contracts worth more than $30 million, to procure antibodies from horses for use in manufacturing a heptavalent botulism antitoxin. These included contracts to the Auburn University College of Veterinary Medicine, in Auburn, Alabama ("Auburn"), and Lake

Immunogenics, Inc. in Ontario, New York, a small fraction of the recent overall expenditure by the federal government for equine-derived botulism antitoxin. In 2006, the government awarded a contract for $362 million, plus an additional $234 million payable at the government's discretion, for the final processing and manufacture of 200,000 doses of the heptavalent botulism antitoxin for delivery to the Strategic National Stockpile.

19. As a result, hundreds of horses have been used to produce botulism antitoxin in recent years. The government and its contractors seek to portray the process as benign to the horses, claiming, for example, that the horses used in these procedures feel "no more pain than a human feels when giving blood."

20. In fact, the horses subjected to these invasive procedures suffer severely, as is attested to in a multitude of published scientific and medical reports dating as far back as 1900. The repeated injections of toxins and oil-based adjuvants cause extensive localized tissue damage in the form of necrosis, abscesses, fistulas, and tumors, and invariably result in an irreversible degeneration of the liver, spleen, and kidneys – frequently leading to rupture of one or more organs, massive internal hemorrhaging, and an agonizing death. To obtain the horses' antibodies, large volumes of their blood are removed on a regular basis by automated transfusion, during which they are heavily sedated with intravenous tranquilizers, forcibly immobilized in metal stocks – with their heads restrained in slings, their necks tourniqueted, and their jugular veins implanted with catheters – for 6-8 hour durations, inflicting them with chronic anemia, protein deficiencies, and other debilitating effects of massive blood depletion. They also suffer ataxia, blindness, cerebral perfusion, neuro-muscular dysfunctions, traumatic shock, and sudden death caused by the procedure itself. The extreme pain, physiological deterioration, and violent deaths suffered by the horses are direct

consequences of using them as "living factories" for production of antitoxins for treatment of humans.

2. The Fund's September 2009 FOIA Request

21. Seeking to understand the extent of the government's use of horses to create antitoxin and related products, in September 2009, the Fund sent Defendants a FOIA request seeking records related to the government's use of horses for "antitoxin and analogous products," from 2003 forward.

22. Over four months later, Defendants responded by complaining that responding to the Fund's straightforward request would require review of "an unlimited number of records, and the technical interpretation of thousands of contracts, grants, interagency agreements, [and] cooperative agreements." On that basis, Defendants *refused* to respond to the request as written, and instead insisted that the Fund narrow the request.

23. Although it was, and remains, unclear as to why Defendants are unable to respond to the Fund's original request, in an effort to expedite the process and at least *start* receiving responsive records, in January 2010, the Fund requested that Defendants *initially* search for and provide the following list of records:

a. Records related to CDC's Solicitation for Proposal that led to the Auburn contract award

b. Records related to Auburn's proposal

c. Records related to the contract between CDC and Auburn regarding the ESPP

d. Records related to CDC's risk assessments regarding potential effects on horses of the procedures proposed in the ESPP contract

e. Records related to CDC's contract award decision

f. Records related to CDC's funded research and studies related to the ESPP

g. Records related to CDC's goals and objectives for the ESPP

h. photographs and video of horses involved in the ESPP.

The Fund explicitly stated that it was not seeking any information – covered by the Security Act – that would identify individuals possessing listed agents or toxins or their location or related information, or any safeguards or security measures being used to prevent unauthorized access to such information.

3. Defendants' Response To The FOIA Request

24. Although the Fund had in good faith considerably narrowed its request to at least *begin* the process of receiving requested records, and continued in good faith to provide clarifying information to assist Defendants in compiling responsive records, Defendants nonetheless complained that the request "is still extremely broad," and failed to produce *any* responsive records.

25. Because, despite the Fund's efforts, Defendants continued to ignore the Fund's request, in April 2010, the Fund filed a formal administrative appeal of the constructive denial of the FOIA request, as provided by 5 U.S.C. § 552(a)(6).

26. In May 2010, HHS wrote to the Fund claiming that CDC would begin to release records and would continue to do so "on a rolling basis," and asserting that, on that basis, the agency was closing the FOIA appeal. However, in fact the only records provided were *publicly available information* that the Fund itself had submitted to Defendants to help in the search for records the Fund seeks.

27. Although Defendants claimed that portions of the FOIA request had been forwarded to certain offices within HHS, Defendants also refused to answer the Fund's inquiries on the status

of those referrals. Finally, in July 2010, HHS informed the Fund that several offices had conducted searches for responsive records, and that the CDC FOIA office would be conducting a "line by line review" before releasing responsive records "on a rolling basis." HHS also stated that responsive records from the Office of the Secretary would be released in several weeks, and CDC stated that certain records had been referred to the original submitters in order to allow them to identify commercial information or financial material that might be exempt from disclosure.

28. On July 20, 2010, the Fund received a substantive response from the HHS Office of the Secretary, concerning only eighty-nine pages of responsive records. HHS withheld most of the contents of these records on the basis of, *inter alia*, (a) the exemption for records prohibited from disclosure by another statute (Exemption 3); (b) trade secrets and confidential information (Exemption 4); (c) the deliberative-process privilege (Exemption 5); and (d) the privilege for records the release of which would constitute a clearly unwarranted invasion of personal privacy (Exemption 6).

29. On August 18, 2010, CDC sent another determination on the FOIA request, withholding 419 pages *in their entirety*. These records were withheld on the basis of the exemption for records prohibited from disclosure by another statute (Exemption 3), trade secrets and confidential information (Exemption 4), and the deliberative-process privilege (Exemption 5).

4. Plaintiff's Second FOIA Appeal

30. In light of the serious deficiencies in Defendants' response, the Fund filed another administrative appeal. In that appeal, the Fund explained in detail that Defendants had not met their burden to demonstrate that the FOIA exemptions they had invoked permit Defendants' massive withholdings of responsive records.

31. The Fund explained, *inter alia*, that Defendants had not demonstrated that other statutes – i.e., the PIA, 41 U.S.C. § 423, and the Security Act, Pub. Law 107-188 – allow withholding responsive records under Exemption 3. Because the contract at issue was not conducted through competitive bidding procedures, the Fund explained that the PIA does not apply. Similarly, the Security Act does not apply to the Fund's request, which concerns well-known procedures for generating antitoxins, and which explicitly excluded any information exempt from disclosure under the Security Act – such as individual names.

32. The Fund also explained that the Defendants had not demonstrated that: withheld records, in fact, contain trade secret or confidential information subject to Exemption 4, particularly given that the techniques and procedures used to generate equine antitoxin have been in the public domain for over a century; that records withheld under Exemption 5 are pre-decisional and deliberative materials; or that release of any records would constitute an unwarranted invasion of privacy under Exemption 6.

33. The Fund also explained that Defendants have completely failed to conduct a reasonable search for responsive records. The Fund's September 2009 FOIA request seeks information about the government's use of horses for "antitoxin and analogous products." Defendants have never purported to search for all of these records, including records under Defendants' control that may be in the possession of Defendants' contractors.

34. Defendants have not even claimed to have completed their search for the narrower set of records the Fund identified in January 2010, in an effort to at least begin Defendants' search for responsive records. The contract with Auburn University requires monthly reports and a multitude of other federal reporting requirements that would discuss, *inter alia*, details about the hundreds of

horses being used in the ESPP there, including their acquisition, number, genders, average size and weight, the injections they are receiving, and their health status. These records have not been produced. Defendants also claimed there were no records related to assessments of possible pathologic effects to the horses of the procedures being done on them to produce botulism antitoxin, even though the Statement of Work for the contract requires that this kind of information be maintained, including, *inter alia*, blood chemistry panels, rectal temperature thresholds, and plasma protein levels. The Defendants also failed to search for and produce photographs or video of the use of horses for antitoxin production, even though equine veterinary facilities uniformly utilize such methods to record and describe the kind of procedures being undertaken in this project.

35. On December 21, 2011, Defendants informed the Fund by letter that they were considering the Fund's appeal and would "issue a final response shortly." On February 14, 2011, Defendants sent another response, purporting to deny the appeal in some respects, and explaining that the Fund "may seek judicial review in the district court of the United States in which you reside . . . ." At the same time, Defendants claimed that review of "additional records" is ongoing. The Fund has received no further communications to date from Defendants in this matter.

PLAINTIFF'S CLAIM FOR RELIEF

36. By failing to search for and provide all records responsive to the Fund's September 2009 FOIA request, or even the narrower January 2010 list of record requests that the Fund submitted in an effort to at least *begin* the production of records; unlawfully withholding records under FOIA exemptions; failing to segregate responsive records as required to provide non-exempt information; and failing to timely resolve Plaintiff's appeal, Defendants are violating the FOIA. Id. §§ 552(a)(3)(A), (6)(A)(ii).

37. Plaintiff has a right to obtain the requested records.

Wherefore, Plaintiff respectfully requests that this Court:

1. declare Defendants in violation of the FOIA;

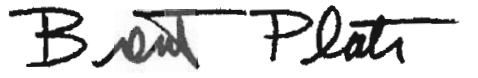
2. order Defendants to release to Plaintiff within twenty days all records responsive to the Fund's FOIA request withheld on exemption grounds;

3. order Defendants to conduct a reasonable search for, and release to Plaintiff, all additional non-exempt records, and parts of records, responsive to the Fund's FOIA request within twenty days;

4. award Plaintiff their costs and attorneys' fees; and

5. award Plaintiff such other and further relief as the Court may deem just and proper.

Respectfully submitted,



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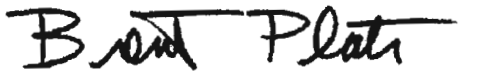
Attorneys for Plaintiff

June 7, 2011

CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Pursuant to Civil L.R. 3-16, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding: None.

Respectfully submitted,



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